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**Report Highlights:**

The EU's authorization system for Genetically Modified Organisms (GMOs) remains extremely slow. Only two applications for import had been authorized by June, 2013. However, on September 26, the EU Court of Justice (ECJ) ruled in favor of Pioneer Hi-Bred International Inc, stating that the European Commission "had failed to meet its obligations." As a result, the College of the Commissioners requested the Environment Council to authorize the cultivation of Pioneer Bt 1507 corn. We understand that the Ministers will probably address this issue in January 2014. The College also adopted three other import applications on November 6.

## **General Information:**

### **Introduction**

On June 25, two import applications were authorized (extension of the scope for its use) for the German company Bayer: Bayer MS8, RF3 & MS8 X RF3 and a renewal for the authorization of Bayer MS8 X RF3 rapeseed events. The EU's authorization system for GMOs remains extremely slow and the number of applications continues to exceed the number of approvals. As of November 2013, a backlog of 68 applications (for approval of import, renewal, and cultivation) remains pending in the EU approval system, which has the effect of blocking U.S. exports of certain agricultural products. If the current rate of approval continues, the backlog of pending products will increase to 106 by 2020. About 6 applications for cultivation were already withdrawn in 2013.

### **The European Court of Justice's (ECJ) Decision**

Attempts to improve timelines seem to have little or no effect and product applications are usually not processed within the timeline prescribed by the comitology procedure.

However, on September 26, 2013, the ECJ ruled in favor of Pioneer Hi-Bred International Inc, regarding the authorization of its Bt 1507 corn submitted in 2001. This case dates back to May 2007, when Pioneer filed a complaint against the Commission for delaying authorization of its Bt 1507 corn despite 6 positive opinions by the European Food Safety Authority (EFSA).

The application was finally put to a vote at the Standing Committee for Food Chain and Animal Health (SCoFAH) in the Regulatory Committee, comprised of experts from the Member States (MS), in February 2009, which did not reach a qualified majority for or against. Further to this "no opinion" the Commission failed to put the matter to vote in Council "without delay". The Commission's inaction for over four years was severely criticized by the ECJ. Furthermore, the ECJ also criticized the Commission for unnecessarily resubmitting the Pioneer application to EFSA seven times between 2001 and 2009. The Court's decision on Pioneer Bt 1507 corn confirms the urgency of reconciling strict and predictable European authorization rules for GM cultivation, with fair consideration of national contexts.

While the ECJ ruling may result in the acceleration of the application process, it will not necessarily lead to more approvals. Even with an EU GM cultivation approval, some Member States, including Germany, France, Hungary, Greece, Luxemburg, Bulgaria, and Hungary, which disagree with plant biotechnology for reasons other than science, still ban cultivation on spurious scientific grounds. Only two GM events have been approved for cultivation in the EU (MON 810 and Amflora Potato) and the Pioneer cultivation application was submitted 12 years ago. For more information, please see the following [press release](#).

### **The Process for GMOs Cultivation Applications**

The procedure for approving GMOs for cultivation differs slightly from the approval process for imports of GM food and feed. The main difference is that the regulations governing approval for import applications set clear timelines by which the Commission is required to put product applications on the agenda of the relevant committees. According to Regulation (EC) 1829/2003, Art 7 and Council Decision 1999/468/EC Art 5.4, the Commission has a maximum of 3 months to ask the MS to vote on events that already have a favorable EFSA opinion. If the vote does not reach the required qualified majority (260/352), another vote must be taken in the Appeal Committee within 2 months. In practice, the approval process clearly exceeds the legal limits. A recent industry assessment estimated that it takes about 48 months for a new GM event to be approved for import into the EU. On the other hand, the cultivation applications need to be put to the vote "without delay." If no qualified majority is reached at Council, the Commission may adopt its proposal or not.

### **The College of Commissioners Refer Cultivation Request to Council**

On November 6, following the ECJ ruling that the Commission had failed to act, the College of the Commissioners referred a request to authorize cultivation of Pioneer Bt 1507 corn to the Council. We understand that it is unlikely that the request will be discussed during the Environment Council meeting scheduled for December 13, 2013, and will probably be discussed during the Agricultural Council meeting scheduled for January 27-28, 2014.

The College of the Commissioners also adopted the following import applications on November 6, 2013:

- Pollen produced from MON 810 corn for food (in line with the "GM honey" issue);
- MON89034×1507×MON88017×59122 corn stack plus combinations for food/feed import and processing;
- MON89034×1507×NK603 corn stack for food/feed import and processing.

### **Proposal to allow Member States to "opt out" cultivating EU approved biotech crops**

Further to the College of the Commissioners' recent referral of the request to authorize cultivation of Pioneer Bt 1507 corn, the Commission has requested a fresh debate on its "cultivation proposal" which is designed to allow MS to decide whether or not to allow the cultivation of approved biotech crops in their individual territories. The proposal requires approval by the Council and the Parliament. We understand that the proposal is likely to be discussed at the Environment Council scheduled for December 13, 2013. To date, there is not common position between the two institutions. However, the European Parliament has already adopted its opinion which would allow MS to restrict or prohibit cultivation of GMOs in their own territory on grounds other than those relating to risks to health and the environment (a safeguard clause) despite EFSA's positive opinions.

**EFSA Adopts An Inconclusive Opinion On GM 59122 Corn Cultivation Application Due To Its Potential Adverse Effects Of Non-Target organisms (NTOs)**

On November 21, 2013, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms published a supplementary statement to its original positive opinion for GM 59122 corn cultivation application. As expected, the original positive opinion for its cultivation has become inconclusive, but there will be no impact on the positive assessments of 59122 corn regarding human and animal health. Therefore, the inconclusive opinion does not change the current EU approval for corn for food, feed, and imports.

**According to EFSA's statement,** *"The Panel is no longer in a position to complete its assessment on the occurrence of adverse effects on pollinators. The Panel reassessed the available dataset on ladybirds, including the Califf and Ostrem (2009) study, and considers the latter study does not enable resolving the remaining scientific uncertainty on the potential toxicity of the binary Cry34Ab1/Cry35Ab1 proteins on Coccinella septempunctata or other ladybirds. In both cases, the Panel recommends that an additional laboratory study is performed prior to authorization."*

GM 59122 corn is approved for food and feed use in more than 40 countries around the world including the EU.

In January 2005, the applicant submitted an application for GM corn cultivation in the EU. On March 21, EFSA adopted a positive safety opinion for its cultivation; however the opinion has now become inconclusive.

Here is the link of the updated EFSA supplementary statement on GM 59122 corn cultivation application file: <http://www.efsa.europa.eu/en/press/news/131121.htm>

**For more information on EU Agricultural Biotechnology, please see the [GAIN EU-27 2013 Agricultural Biotechnology Annual Report](#)**